

REMARKS

Status of the Claims

Claims 38-43 are pending in the present application. Claims 44, 45, and 113-122 have been cancelled without prejudice to or disclaimer of the subject matter contained therein. Applicants expressly retain the right to file continuing applications directed to the deleted subject matter. Claims 113 and 121 are cancelled due to the restriction requirement. Claims 1 and 39 have been amended as described elsewhere herein. Support for the amendments may be found in original specification and claims as filed, including, for example, in original claim 45. No new matter has been added by way of amendment.

The Examiner is respectfully requested to withdraw the rejections and allow claims 38-43. In any event, the Examiner is requested to enter the above amendments for the purposes of further prosecution. These amendments were not made earlier because Applicants earnestly believe that the specification is enabling for the breadth of the claims as originally drafted.

The Rejection Under 35 U.S.C. § 112, Second Paragraph, Should be Withdrawn

The rejection of claims 44 and 115-120 under 35 U.S.C. § 112, second paragraph on the grounds that these claims are indefinite. Claims 44 and 115- 120 have been cancelled to expedite prosecution, thereby rendering the rejection of these claims moot. Accordingly, withdrawal of the rejection is requested.

The Rejections Under 35 U.S.C. § 112, First Paragraph, Should be Withdrawn

Claim 38-45 and 114-120 have been rejected under 35 U.S.C § 112, first paragraph, on the grounds that these claims contain new matter. The rejection is not well founded because, as previously indicated in the Amendment mailed October 13, 2006, the original specification and claims, including paragraph 112 of the specification and original claim 38, provide literal support for the expanded binding pocket recited in

the claim 38. In any case, claim 38 has been amended to recite that the GR polypeptide structure has the atomic coordinates shown in Table 2, thereby obviating the rejection of this claim and dependent claims 39-43. Claims 44, 45, and 114-120 have been cancelled to expedite prosecution, thereby rendering the rejection of these claims moot.

The Examiner has maintained the rejection of claims 38-43, 45, 114, and 120 under 35 U.S.C. § 112, first paragraph on the grounds that these claims are not supported by a sufficient written description. The rejection is not well-founded because, as noted in the amendment filed October 13, 2006, the invention recited in these claims is supported by two examples of the actual reduction to practice of the method recited in claim 38, by numerous drawings of the expanded binding pocket recited in claim 38, and by a recitation of the relevant structural features that characterize this expanded binding pocket. Accordingly, the Office has not established a *prima facie* case showing that at the time the application was filed, one skilled in the art would not have recognized that the inventor was in possession of the invention as claimed in view of the disclosure of the application as filed. In any case, claim 38 has been amended to recite that the GR polypeptide structure has the atomic coordinates shown in Table 2, thereby obviating the rejection of this claim and dependent claims 39-43. Claims 44, 45, and 114-120 have been cancelled to expedite prosecution, thereby rendering the rejection of these claims moot.

The rejection of claims 38-43, 45, 114, and 120 under 35 U.S.C. § 112, first paragraph, on the grounds that the claimed invention does not provide sufficient enablement to allow one of skill in the art to make and use the claimed invention has been maintained. The rejection is not well founded because, as noted in the amendment filed October 13, 2006, the Office has not established that undue experimentation would be required to practice the claimed methods in view of the breadth of the claims (which are directed to methods of identifying GR modulators using a GR polypeptide structure having an expanded binding pocket having defined structural characteristics), the amount of direction provided in the specification (which

provides extensive guidance for practicing the methods as described in the previous Amendment), the presence of multiple working examples, the prior art (which teaches methods for designing and modeling ligands based on the three-dimensional structure of the ligand binding site), and the high level of skill of those in the art. In any case, claim 38 has been amended to recite that the GR polypeptide structure has the atomic coordinates shown in Table 2, thereby obviating the rejection of this claim and dependent claims 39-43. Claims 44, 45, and 114-120 have been cancelled to expedite prosecution, thereby rendering the rejection of these claims moot.

In view of the above arguments and amendments, all grounds for rejection under 35 U.S.C. § 112, first paragraph, have been overcome or obviated. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

The Rejection under 35 U.S.C. § 103 Should be Withdrawn

The rejection of claims 38-45 and 114-120 under 35 U.S.C. § 103(a) has been maintained on the grounds that recitation of atomic coordinates in these claims should not given patentable weight in construing the claims, and that claims 38-44 and 114-120 are therefore obvious in view of Apolito *et al.* (WO 03/015692), Gillner *et al.* (WO 00/52050), and claim 45 is obvious in view of Apolito *et al.*, Gillner *et al.*, and Hogger *et al.* (1994) *Steroids* 59(10):597-602. Claims 44, 45, and 114-120 have been cancelled to expedite prosecution, rendering the rejection of these claims moot. The rejection of claims 38-43 is respectfully traversed for the reasons described below.

The Examiner argues that the recitation of structural coordinates in claims 38-45 and 114-120 constitutes nonfunctional descriptive matter and that this claim limitation should not be considered in construing the claims. Applicants again reiterate that the present invention is not directed to a mathematical algorithm, a computer readable medium, or a compilation of data. Rather, the instant claims directed are to methods of using structural information about a novel GR expanded binding pocket in the design of GR modulators. The atomic coordinates recited in the claims describe structural information about the novel GR expanded binding pocket structure, and this

structural information is used in the claimed method to identify GR modulators. The claims depend on the use of the novel structural information to achieve the recited purpose of the claim, *i.e.*, the identification of a glucocorticoid receptor modulator. Accordingly, there is a functional relationship between the structural coordinates and the recited method of identifying a glucocorticoid receptor modulator, and the recited limitation must be considered in construing the claims for the purposes of determining patentability.

The Examiner argues that the rejection is supported by *In re Gulack* 703 F.2d 1381 (Fed. Cir. 1983). However, in *Gulack*, the Federal Circuit cautioned against a liberal application of "printed matter rejections," stating:

A "printed matter rejection" under § 103 stands on questionable legal and logical footing. Standing alone, the description of an element of the invention as printed matter tells nothing about the differences between the invention and the prior art or about whether that invention was suggested by the prior art.

Id at 1385 n.8. Based on the facts of *Gulack*, which the applicants previously described in the Amendment mailed October 13, 2006, the Federal Circuit found that the printed matter recited in the appealed claim was functional and rendered the claimed invention patentable, stating:

The differences between the appealed claims and Witcoff reside in appellant's particular sequence of digits, and in the derivation of that sequence of digits. These features are critical to the invention disclosed by the appealed claims. Witcoff neither discloses or suggests either feature.

Id at 1387.

In *In re Lowry*, 32 F.3d 1579 (Fed. Cir. 1994), which is also cited by the Examiner in support of the rejection, the Federal Circuit considered whether a claim limitation reciting attribute data objects (ADOs) stored in memory should be given patentable weight in construing the claim. The court held that the recitation of the ADOs was not analogous to printed matter because the data structures depended only functionally on

information content . *Id.* At 1583. The court also stated that even if the data structures had been analogous to printed matter, the Board had failed to establish a *prima facie* case of obviousness. The court stated, "[i]n sum, the ADO's perform a function. Gulack requires no more." *Id.* At 1584, *citing Gulack*, 703F.2d at 1386.

In the present application, the recited method of identifying a glucocorticoid receptor modulator depends functionally on the coordinates describing the GR polypeptide structure comprising an expanded binding pocket. Accordingly, the description of the structure of a glucocorticoid receptor having an expanded binding pocket is critical to the claim and must be considered to properly construe the claim's scope. Apolito *et al.*, Gillner *et al.*, and Hogger *et al.*, either alone or in combination, neither teach nor suggest the all of the limitations of claims 38-43 when properly construed.

In view of the above arguments, all grounds for rejection under 35 U.S.C. § 103 have been overcome. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

CONCLUSION

It is believed that the current application is now in condition for allowance. Early notice to this effect is solicited. If, in the opinion of the Examiner, an interview would expedite prosecution, the Examiner is invited to call the undersigned.

Applicants believe that no fees are due in connection with the filing of this paper other than those specifically authorized herein. However, should any other fees be deemed necessary to effect the timely filing of this paper the Commissioner is hereby authorized to charge such fees to Deposit Account No. 07-1392.

Respectfully submitted,

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